IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF NEW MEXICO

THOMAS M. STEINBERG, JR., and
AMY M. STEINBERG, et al.,

Plaintiffs,

v. No. CIV 02-950 JC/LFG

CRYOLIFE, INC.,

Defendant.

MEMORANDUM OPINION AND ORDER GRANTING IN PART AND DENYING IN PART PLAINTIFFS' THIRD MOTION TO COMPEL

Introduction

THIS MATTER is before the Court on Plaintiffs' Third Motion to Compel responses to their Fourth Request for Production, filed March 7, 2003. [Doc. 58]. Defendant CryoLife Inc.'s ("CryoLife's") response was filed March 21, 2003, and Plaintiffs' reply was filed April 2, 2003. [Docs. 64, 70.] After careful consideration of the pleadings and pertinent law, the Court concludes that the Motion will be granted in part and denied in part.

Background

This is a negligence and products liability case involving the death of Sydney Steinberg, Plaintiffs' five-year old daughter. Sydney suffered from heart problems at birth, and in December 1999, underwent donor heart valve implantation at the University of New Mexico Hospital. The

donor heart valve, obtained from a nine-year old donor who died as a result of an accident, was processed by Defendant CryoLife before it was implanted. CryoLife has been involved in the business of human tissue processing since 1984, and over the years, claims to have processed more than 60,000 non-heart valve tissues and more than 16,000 heart valves which are used by surgeons in various reconstructive procedures.

After the implantation procedure, Sydney appeared to improve. Subsequently, her parents relocated to Oregon and Sydney's care was transferred to a heart clinic in that state. While in Oregon, it was discovered that Sydney had a fungal growth on the heart valve. In June 2000, Sydney underwent a second implant procedure in Oregon, where the prior heart valve was removed and a new one, processed by a different processing company, was implanted. Initially, Sydney improved, but the fungal infection reappeared and she died in December 2000.

Plaintiffs contend that the CryoLife valve was contaminated with arthrographis kalarae when it was provided to Sydney's surgeons for implantation and that this fungal contamination led to Sydney's infection, which over time led to a systemic fungal endocarditis that resulted in her death. Part of Plaintiffs' theory is that CryoLife engaged in improper harvesting, procurement, manufacture and testing of the heart valve before it was implanted. Plaintiffs seek an award of compensatory and punitive damages from CryoLife.

CryoLife asserts that the fungus grown on the heart valve explanted from Sydney in June 2000 was an extremely rare form of fungus and that CryoLife had no reported cases of that type of fungal infection prior to Sydney's death. CryoLife states that it is unaware of any reported cases of fungal endocarditis resulting from arthrographis kalarae. It appears that CryoLife will attempt to defend this case by attempting to show that the contamination could have occurred during the surgical procedure,

during the post-surgical hospitalization at UNM Hospital, or through an environmental exposure of Sydney to fungal spores. The same donor who supplied the heart valve to Sydney in New Mexico provided a companion heart valve for another recipient who did not develop any fungal infection or complications.

Plaintiffs' Third Motion to Compel concerns discovery disputes regarding the FDA's 2002 inspection of CryoLife and more specifically, information generated from a September 5, 2002 written agreement entered into by both CryoLife and the FDA. [Doc. 64, Ex. D.] According to CryoLife, the FDA investigation and subsequent recall of tissues ensued after reports of three deaths that resulted from patients implanted with orthopedic tissue during knee surgeries in Minnesota. CryoLife maintains that the FDA recall involved only non-cardiac tissues. CryoLife also asserts that only one of the three knee surgery patients received a CryoLife processed tissue, even though the FDA continued its investigation of CryoLife. Based on documentation attached to earlier motion to compel pleadings, it appears true that most of the CryoLife tissues found to have had problems involved non-heart valve tissue. In March 22, 2002, however, the Centers for Disease Control and Prevention ("CDC") informed CryoLife that it had received a report of a patient who acquired fungal endocarditis following implantation of an aortic valve and conduit supplied by CryoLife. By May 2002, the CDC notified CryoLife that the total number of infections found to be associated with CryoLife allografts was 21, again almost all of which involved non-cardiac tissues. During the ongoing investigation, the FDA and CDC made recommendations to CryoLife to improve its tissue processing and testing procedures. As of April 12, 2002, CryoLife had not adequately implemented the CDC's recommendations. On June 17, 2002, the FDA issued a warning letter listing deficiencies at CryoLife including matters related to CryoLife's processing of heart valves. CryoLife's June 25,

2002 response did not provide adequate assurance to the CDC that it had addressed the deficiencies. On July 6, 2002, CryoLife acknowledged that the heart valve about which it was notified in March 2002, was the likely source of the serious adverse event, and further that the heart valve was processed and tested by the same methods that CryoLife used in processing non-heart valve tissues. *See* Exhibits to the First and Second Motions to Compel.

On August 13, 2002, the FDA issued an Order for Retention, Recall and/or Destruction, which CryoLife states essentially prohibited it from engaging in its tissue processing operations. [Doc. 64, p. 4.] Subsequently, on September 5, 2002, the President and CEO of CryoLife and the Acting Director of the FDA signed an agreement which allowed CryoLife to distribute limited types of previously processed tissues under certain conditions. [Id.; Doc. 64, Ex. D.] For example, the 3-page Agreement permitted CryoLife to provide certain tissues for medically urgent use "when all alternative treatments" were exhausted or were unavailable, and when certain enumerated conditions were met. The list of tissues that could be distributed included non-valved cardiac conduits and patches, and other specific veins and arteries. [Id.]

The Agreement required that CryoLife perform pre-processing (before antimicrobial treatment) cultures on all incoming tissues. CryoLife also agreed to perform certain types of reviews of its testing records and complaint files and to implement specified interim procedures to help prevent infectious disease contamination or cross-contamination of tissue. [Ex. D.] CryoLife had to engage a consultant/third party reviewer to assist it in developing a corrective action plan to validate its processing procedures. The Agreement was to remain in effect for 45 days, at which point the FDA would review records and information to determine whether the agreement should be

renewed or modified. [Ex. D, p. 3.] CryoLife states that the Agreement has been renewed and has been modified from time-to-time by agreement of CryoLife and the FDA. [Doc. 64, p. 5.]

Legal Standard

Rule 26 is the starting point in analyzing discovery disputes. It is clear that after the 1993 and 2000 Amendments to the rules, the term "relevancy" is no longer as broadly construed as it once was, and further, that discovery is not without limits. Rule 26 expressly contemplates the limitation of discovery if the burden or expense of the proposed discovery outweighs its likely benefits, "taking into account the needs of the case, the amount in controversy, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues." Fed.R.Civ.P. 26(b)(2)(iii); Burka v. U.S. Dept. of Health and Human Services, 87 F.3d 508, 517 (D.C. Cir. 1996). After consideration of the needs of the parties, the court may, its exercise of discretion, deny discovery completely, limit the conditions, time, place or topics of discovery, or limit the manner in which information is to be revealed. Burka, 87 F.3d at 518.

Thus, the Court is mindful of the need to balance one party's right of discovery with an opposing party's right to be free from intrusive and burdensome discovery. Koch v. Koch Industries, Inc., 203 F.3d 1202, 1238 (10th Cir.), *cert. denied*, 531 U.S. 926, 121 S.Ct. 302 (2000). "Indeed, the 1983 and 1993 Advisory Committee Notes [to Rule 26(b)(2)(iii)] indicate this sub-section was added 'to encourage judges to be more aggressive in identifying and discouraging discovery overuse' and 'to enable the court to keep tighter rein on the extent of discovery.'" Id.

Moreover, due to abusive, unchecked litigation practices that significantly increased the costs of litigation, congested court dockets, and contributed to delay the final disposition of litigation, Congress enacted the Civil Justice Reform Act of 1990 ("CJRA"), 28 U.S.C. § 471, *et seq.* The

goals of the CJRA are to expedite the ultimate disposition of litigation and to reduce the costs. These goals are accomplished by close judicial scrutiny of the discovery process, establishment of case management deadlines, and utilization of alternative dispute resolution procedures.

Shortly after the adoption of the CJRA, the Federal Rules of Civil Procedure were modified to dovetail with the CJRA. Indeed, Rule 1 of the revised rules adopts the two-pronged CJRA goals as part of the Rules' purpose. "They [civil rules] shall be construed and administered to secure the just, speedy, and inexpensive determination of every action."

In addition, recent modifications to the federal rules further limit the scope of discovery. For example, Rule 26 previously provided, "Parties may obtain discovery regarding any matter, not privileged . . . ." The revised rule now provides, "Parties may obtain discovery regarding any matter, not privileged, that is relevant to the claim or defense of any party . . . ." This rule change signals a narrower scope of permissible discovery than existed before. Therefore, a party is not permitted to plead its allegations in indefinite terms and then conduct broad discovery hoping to benefit from a fishing expedition. Koch, 203 F.3d at 1238; Fed.R.Civ.P. 26, advisory committee notes.

With this balancing process in mind, along with the goal of providing closer judicial scrutiny over the discovery process, the Court now addresses the three discovery disputes identified by Plaintiffs in their Third Motion to Compel.

Analysis

Request for Production No. 66 asks CryoLife to produce "all information and data you obtained or generated as a result of the agreement entered into between CryoLife and the FDA . . . including but not limited to the results of testing by any independent certified testing labs . . . ." CryoLife objected on grounds that the request was over broad, unduly burdensome, not reasonably

limited to the subject matter and not reasonably calculated to lead to the discovery of admissible evidence. CryoLife also objected on grounds of attorney-client privilege, work product and self critical analysis. In addition, CryoLife argued that the materials constituted confidential proprietary information and/or trade secrets, and that to produce documents related to the FDA's ongoing regulatory/enforcement action would invade CryoLife's due process rights.

Based on these objections, Plaintiffs agreed to limit Request No. 66 to documentation related to certain paragraphs in the Agreement, and further stated that the materials could be limited to factual agreements and corresponding documents between CryoLife and the FDA. Plaintiffs clarified that they do not request notes from CryoLife's counsel or subjective evaluative materials protected by the self critical analysis doctrine. Rather, they seek documentation containing objective data.

Plaintiffs seek documentation related to paragraphs 3, 4, 5 and 7 of page 2 of the Agreement and paragraphs 1, 2 and 3 on pages 2 and 3 of the Agreement. Page 2, Paragraph 3 states that "CryoLife will contact Tissue and Organ Procurement Organizations or other facilities that procured the tissues described above [tissues listed on page 1 that may be distributed for specified medical uses] to ascertain if microbial cultures were performed during or after procurement; if cultures were performed, CryoLife will obtain documentation of the results of that testing . . . ."

The Court does not see how the documentation related to paragraph 3 is reasonably calculated to lead to the discovery of admissible evidence. For one thing, the referenced tissues may come from facilities other than the one that provided the cardiac tissue for Sydney's implant. Secondly, the Court cannot see that any such information would further illuminate the central issues in this case, in addition to what the Court already has ordered produced in its previous Order that addressed Plaintiffs' First Motion to Compel.

In balancing what it perceives to be Plaintiffs' limited need for the requested discovery against CryoLife's right to be free from intrusive and burdensome discovery, the Court sustains CryoLife's objection with respect to paragraph 3 of the Agreement.

Page 2, Paragraphs 4 and 5 require CryoLife to perform a retrospective review of its own pre-packaging microbiological testing records for all associated tissue and to perform a search of its complaint files to determine if there are any complaints regarding infections for all associated donor tissue. The Court assumes that "associated tissue" refers to the list of tissues on page 1 of the Agreement that CryoLife may distribute under certain conditions. While such materials may have no relevancy to the processing of Sydney's tissue and may not be admissible at trial, Plaintiffs' theory concerns, in part, CryoLife's pre-packaging and processing methods. Plaintiffs assert that there is documentation showing that CryoLife processed cardiac and non-cardiac tissue alike, at least as of 1997. Thus, these requests may be reasonably calculated to lead to the discovery of admissible evidence, and the Court will order CryoLife to produce responsive documents in relation to paragraphs 4 and 5 of the Agreement.

To the extent that CryoLife contends that any of the materials are protected by a recognized privilege, CryoLife should produce an appropriate privilege log, as described in the Court's Order addressing the First Motion to Compel. The production also may be narrowed in accordance with Plaintiffs' agreement that they do not seek subjective evaluative materials or attorney notes and impressions.

The Court rejects CryoLife's argument that its due process rights will be violated if required to provide some of the requested documentation. CryoLife provides no legal support for this position under these circumstances, nor is the Court aware of any. Moreover, CryoLife has not demonstrated

how production of the requested information would interfere with the FDA's enforcement process or with CryoLife's ability to work with the FDA. Finally, any privacy or confidentiality concerns should be adequately addressed by the parties' Confidentiality Order.

Page 2, Paragraph 7 of the Agreement directs CryoLife to document and maintain records of its actions under this agreement and to make those records available for FDA review. Paragraph 7 appears to encompass all documents generated with respect to the Agreement. As indicated above, the Court does not consider all documents that might be generated in relation to this Agreement to be relevant to this lawsuit. Thus, the Court will not require CryoLife to respond to the document request related to paragraph 7.

Page 2, Paragraph 1 states that "CryoLife will perform pre-processing cultures on all incoming tissues prior to antibiotics, disinfectants, or sterilizing agents . . . . All testing of pre-processing samples will be performed by a contract laboratory with validated methods, until such time as CryoLife's test methods are adequately validated . . . ." Page 3, Paragraph 2 requires CryoLife to perform pre-packaging cultures on all tissue made available for distribution, using certain methods. The testing of the pre-packaging samples will be performed by a contract laboratory.

Again, the Court does not see how the requested information related to paragraphs 1 and 2 is reasonably likely to lead to the discovery of admissible evidence. The actual data from testing that CryoLife is now required to perform and/or another lab's verification of that testing do not appear relevant to the claims and defenses in this case. Thus, the Court does not require CryoLife to produce any documents in response to paragraphs 1 and 2.

Page 3, Paragraph 3 requires CryoLife to establish a corrective action plan that includes steps to validate its processing procedures to prevent infectious disease contamination and cross-

contamination of tissue during processing. CryoLife must engage a consultant/third party reviewer to assist it in developing this plan or validation procedures.

Because CryoLife's processing methods are a central issue in this case, matters concerning how CryoLife now must change its processing procedures in order to prevent infectious disease contamination may be highly relevant to Plaintiffs' claims in this case. Required modification of CryoLife's processing methods may or may not reveal previous inadequate processing methods by CryoLife. Thus, the Court directs CryoLife to respond to the request for production in relation to paragraph 3. To the extent that CryoLife contends that its revised processing procedures cannot be discovered because they are subsequent remedial actions, that argument is rejected and further addressed below.

In sum, Plaintiffs' Motion to Compel additional responses to **Request No. 66** is granted in part and denied in part.

Request for Production No. 69 asks for copies of documents, correspondence, and emails generated by Acumen Sciences since it "was hired by CryoLife to help respond to the FDA Form 483 and Warning Letter." CryoLife initially incorporated all of the objections stated in response to Request No. 66. Additionally CryoLife argues that any procedural changes constitute subsequent remedial measures that "are inadmissible."

In its response to the Third Motion to Compel, CryoLife clarifies that Acumen Sciences was not the outside laboratory CryoLife retained to perform cultures in accordance with the Agreement. Instead, Acumen Sciences was the consultant/third party reviewer referred to in the Agreement. Because the phrasing of Request No. 69 is inaccurate (Acumen Sciences was not hired to help

CryoLife respond to the FDA warning letter), CryoLife first argues that there are no responsive documents.

However, while this may be true, CryoLife proceeds to argue the merits of the request, and the Court will also address the merits of the dispute. The Court will order that CryoLife produce all responsive non-privileged documents relating to Acumen Sciences' analysis in modifying or revising CryoLife's processing methods. The Court is not convinced that the privilege of self-critical analysis would protect these materials, because it appears that any such analysis would rest upon or relate to objective data. Any subjective analysis that comports with the requirements of the self critical analysis doctrine may be redacted or withheld, but should be included in a privilege log.

In addition, the Court rejects CryoLife's argument that Federal Rule of Evidence 407 protects subsequent remedial actions from discovery. Rule 407 governs questions of trial admissibility, not pre-trial discovery of information. Jumper v. Yellow Corp., 176 F.R.D. 282, 284 (N.D. Ill. 1997).

> The standard of admissibility established by Rule 407 for evidence of subsequent remedial measures is not the same as that for pretrial discovery. Some courts have failed to make the distinction and denied discovery on the grounds of relevance. The better view is to permit discovery, not only because Rule 407 is essentially a rule of public policy rather than of relevancy, but also because subsequent remedial measures might be admissible to prove a consequential, material fact in issue other than negligence.

Id. (*quoting* 2 Weinstein, Weinstein's Evidence ¶ 407[07] at 407-44 (1996)). Thus, Rule 407 does not apply to protect production of these materials during discovery. The question of trial admissibility is different and not decided by this Court.

To the extent that CryoLife objects to producing some of the documents on grounds of a recognized privilege, CryoLife must produce a privilege log with pertinent information.

Request for Production No. 71 asks for "the Rinse Recovery Qualification Protocol," referred by to CryoLife in a prior supplemental discovery response. CryoLife incorporates the objections set out in response to Request No. 66 and further asserts that this protocol is a draft of a process that constitutes confidential proprietary/trade secret information. According to CryoLife, the protocol was prepared for the purpose of the ongoing FDA regulatory action, and while CryoLife has not yet implemented it, it may do so and is contemplating filing a patent to protect the process. [Affidavit of James Vander Wyk, Ex. E to CryoLife's Response.]

Here, Plaintiffs have knowledge that such a process exists and that it may have been feasible. While Plaintiffs state that the information goes to feasibility, CryoLife does not assert that such a process was not feasible. Moreover, even if Plaintiffs were to make the feasibility argument or to argue that such a process should have been implemented during or prior to the processing Sydney's cardiac tissue, Plaintiffs already seem to have sufficient information to make this assertion based on their presentation in the reply brief. In other words, the Court is not convinced that Plaintiffs need the actual details of this proposed process (that may constitute intellectual property) in order to adequately assert their position. Thus, in balancing Plaintiffs' need for the information and its minimal importance to the issues against the extremely sensitive nature of trade secret information, the Court will sustain CryoLife's objections.

Summary

The Court will grant in part, and deny in part, Plaintiffs' Third Motion to Compel, as explained in detail above. Request for Production No. 82, which was originally in dispute, was withdrawn by Plaintiffs. To the extent that the Court ordered CryoLife to produce certain

documents, those documents should be provided to Plaintiffs within ten days after entry of this Order. Similarly, privilege logs should also be produced, no later than ten days after entry of this Order.

IT IS THEREFORE ORDERED that Plaintiffs' Third Motion to Compel is GRANTED in part and DENIED in part.

Lorenzo F. Garcia
Chief United States Magistrate Judge